IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:	)	
Akira NAKAO et al.	)	
Serial NO.: 10/517,053	)	Art Unit: 1612
Filed: 07/06/2005	)	Examiner: Chris E. Simmons
For: ORAL COMPOSITION	)	

DECLARATION UNDER 37 CFR 1.132

Honorable Commissioner of Patents and Trademarks

Washington, D.C. 20231

Sir:

I, Akira NAKAO, citizen of Japan and residing Osaka, Japan, declare and say that:

1. I graduated from Okayama University, Graduate School of Engineering, Major of Bioengineering Science.

2. From April 1, 1997 up to the present, I have been an employee of Sunstar Kabushiki Kaisha, the assignee of the above-identified application, and I have been engaged in research works in the Oral Care Business Unit, R&D Division of the said company.

3. I am one of the inventors of the above-identified application, and I am familiar with the subject matter thereof.

4. I have read the Office Action mailed February 7, 2008 and the reference cited therein, and I am familiar with the subject matter thereof.

5. To show that the oral composition of the present invention can exhibit unexpected effects from incorporation of microcrystalline cellulose having a specific average particle diameter and a specific surface active agent, the following experiments were conducted at Hamuro R&D Center, Sunstar Kabushiki Kaisha, 5-30-1, Kamihamuro, Takatsuki-shi, Osaka 569-1044, Japan from April 8 to May 20, 2008.

Methods

An oral composition of an attached document was prepared according to a conventional procedure. The oral compositions prepared were evaluated for their shape-holding ability and dispersibility in an oral cavity according to a following procedure.

Shape-holding ability

The oral composition prepared was filled in a tube having an opening of 3mm diameter and discharged from the opening of the tube onto wires on a measurement apparatus (a square metal rack on which a plurality of wires are placed in a rung-manner with different distances) such that it was laid on the wires. A longest distance of wires where the oral composition was not cut and dropped after 1 minute was measured. This measurement was repeated six times for each of the oral compositions, and an average of four measurements was calculated, except for the longest and shortest distance (unit: mm). The result is represented in Tables on a basis of the average distance as followings.

◎: 20mm or above ○: 15mm or above and below 20mm

△: 10mm or above and below 15mm ×: below 10mm

Dispersibility in an oral cavity

Organoleptic evaluation of dispersibility in an oral cavity upon the oral composition was actually used was performed by four professionals. Dispersibility in an

oral cavity was evaluated by scoring in five degrees: 5 very good, 4 good, 3 ordinary, 2 bad, 1 very bad, and averaging scores. The result is represented in the Table as followings.

◎:	4.5 or above	○:	3.5 or above, below 4.5
△:	2.5 or above, below 3.5	×:	below 2.5

Result and Consideration

Formulation of the oral compositions evaluated and the results of evaluation are shown in attached Tables. In this experiment, an alkyl glucoside (lauryl glucoside) and a betaine (cocamidopropyl betaine) were incorporated as a surface active agent into formulations 1-8 and 9-18, respectively. And, the formulations 1-4 and 9-12 into which 1% of microcrystalline cellulose of an average particle diameter of 5, 9, 20 or 40μm was incorporated, and the formulations 5-8 and 14-17 into which 3% of microcrystalline cellulose was incorporated, were evaluated. Furthermore, the formulations 13 and 18 into which cocamidopropyl betaine and powdered cellulose were incorporated were evaluated.

Although a high shape-holding ability of the oral composition is generally needed such that the oral composition can be easily mounted on a toothbrush, there was a tendency in a conventional technology that the dispersibility in an oral cavity of the oral composition is deteriorated when the shape-holding ability thereof is enhanced.

However, comparing the formulations 1-4 and 9-12, it was confirmed that the formulations 1, 2, 9 and 10 containing 1% of microcrystalline cellulose of an average particle diameter of 5 and 9μm exhibit a superior shape-holding ability and dispersibility in an oral cavity to that of the formulations 3, 4, 11 and 12 containing microcrystalline cellulose of an average particle diameter above 10μm.

Similarly, it was confirmed that the formulations 5, 6, 14 and 15 containing 3% of microcrystalline cellulose of an average particle diameter of 5 or 9μm exhibit a superior shape-holding ability and dispersibility in an oral cavity to that of the formulations 7, 8, 16 and 17 containing microcrystalline cellulose of an average particle diameter above 10μm.

Moreover, comparing the formulations 9 and 10 with the formulation 13, it was confirmed that the formulations 9 and 10 containing microcrystalline cellulose of an average particle diameter of 5 or 9μm exhibit a superior shape-holding ability and dispersibility in an oral cavity to that of the formulation 13 containing powdered cellulose instead of microcrystalline cellulose.

Similarly, comparing the formulations 14 and 15 with the formulation 18, it was confirmed that the formulations 14 and 15 containing microcrystalline cellulose of an average particle diameter of 5 or 9μm exhibit a superior dispersibility in an oral cavity to that of the formulation 18 containing powdered cellulose instead of microcrystalline cellulose.

That is, it was confirmed that the oral composition containing microcrystalline cellulose and either of an alkyl glucoside or a betaine has a superior shape-holding ability and dispersibility in an oral cavity to that of the oral composition containing powdered cellulose instead of microcrystalline cellulose. Particularly, among them, it was confirmed that the oral composition exhibits a particularly superior shape-holding ability and dispersibility in an oral cavity when it contains microcrystalline cellulose having a small average particle diameter such as 5 and 9μm.

6. I further declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true;

and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the above-identified application or any patent issued thereon.

This 2nd day of June, 2008

Akira Nakao

Akira NAKAO

TABLE 1

Ingredient (%)	average particle diameter	formulation 1	formulation 2	formulation 3	formulation 4
		amount (%)	amount (%)	amount (%)	amount (%)
Microcrystalline cellulose	5μm	1.0			
	9μm		1.0		
	20μm			1.0	
	40μm				1.0
Dicalcium phosphate dihydrate		35.0	35.0	35.0	35.0
Hydroxyethyl cellulose		1.4	1.4	1.4	1.4
Sodium carboxymethyl cellulose		0.1	0.1	0.1	0.1
Sorbitol solution		15.0	15.0	15.0	15.0
Concentrated glycerin		3.0	3.0	3.0	3.0
Propylene glycol		3.0	3.0	3.0	3.0
Flavor		1.0	1.0	1.0	1.0
Saccharin sodium		0.3	0.3	0.3	0.3
Titanium oxide		0.5	0.5	0.5	0.5
Lauryl glucoside		2.0	2.0	2.0	2.0
Purified water		remainder	remainder	remainder	remainder
Shape-holding ability		24.0 ◎	21.0 ◎	18.0 ○	18.0 ○
Dispersibility in an oral cavity		4.5 ◎	4.3 ○	3.3 △	3.0 △

TABLE 2

Ingredient (%)	average particle diameter	formulation 5	formulation 6	formulation 7	formulation 8
		amount (%)	amount (%)	amount (%)	amount (%)
Microcrystalline cellulose	5μm	3.0			
	9μm		3.0		
	20μm			3.0	
	40μm				3.0
Dicalcium phosphate dihydrate		30.0	30.0	30.0	30.0
Hydroxyethyl cellulose		1.0	1.0	1.0	1.0
Sodium carboxymethyl cellulose		0.4	0.4	0.4	0.4
Concentrated glycerin		20.0	20.0	20.0	20.0
Flavor		1.0	1.0	1.0	1.0
Saccharin sodium		0.3	0.3	0.3	0.3
Titanium oxide		0.3	0.3	0.3	0.3
Lauryl glucoside		3.0	3.0	3.0	3.0
Purified water		remainder	remainder	remainder	remainder
Shape-holding ability		34.5 ◎	26.3 ◎	27.8 ◎	26.3 ◎
Dispersibility in an oral cavity		4.0 ○	3.5 ○	2.8 △	3.0 △

TABLE 3

Ingredient (%)	average particle diameter	formulation 9	formulation 10	formulation 11	formulation 12	formulation 13
		amount (%)	amount (%)	amount (%)	amount (%)	amount (%)
Microcrystalline cellulose	5μm	1.0				
	9μm		1.0			
	20μm			1.0		
	40μm				1.0	
Powdered cellulose						1.0
Dicalcium phosphate dihydrate		35.0	35.0	35.0	35.0	35.0
Hydroxyethyl cellulose		1.4	1.4	1.4	1.4	1.4
Sodium carboxymethyl cellulose		0.1	0.1	0.1	0.1	0.1
Sorbitol solution		15.0	15.0	15.0	15.0	15.0
Concentrated glycerin		3.0	3.0	3.0	3.0	3.0
Propylene glycol		3.0	3.0	3.0	3.0	3.0
Flavor		1.0	1.0	1.0	1.0	1.0
Saccharin sodium		0.3	0.3	0.3	0.3	0.3
Titanium oxide		0.5	0.5	0.5	0.5	0.5
Cocamidopropyl betaine		1.0	1.0	1.0	1.0	1.0
Purified water		remainder	remainder	remainder	remainder	remainder
Shape-holding ability		25 ◎	20 ◎	17 ○	19 ○	18 ○
Dispersibility in an oral cavity		4.5 ◎	4.5 ◎	3.8 ○	3.8 ○	3.3 △

TABLE 4

Ingredient (%)	average particle diameter	formulation 14	formulation 15	formulation 16	formulation 17	formulation 18
		amount (%)	amount (%)	amount (%)	amount (%)	amount (%)
Microcrystalline cellulose	5μm	3.0				
	9μm		3.0			
	20μm			3.0		
	40μm				3.0	
Powdered cellulose						3.0
Dicalcium phosphate dihydrate		30.0	30.0	30.0	30.0	30.0
Hydroxyethyl cellulose		1.1	1.1	1.1	1.1	1.1
Sodium carboxymethyl cellulose		0.4	0.4	0.4	0.4	0.4
Concentrated glycerin		20.0	20.0	20.0	20.0	20.0
Flavor		1.0	1.0	1.0	1.0	1.0
Saccharin sodium		0.3	0.3	0.3	0.3	0.3
Titanium oxide		0.3	0.3	0.3	0.3	0.3
Cocamidopropyl betaine		1.0	1.0	1.0	1.0	1.0
Purified water		remainder	remainder	remainder	remainder	remainder
Shape-holding ability		35 ◎	26 ◎	21 ◎	24 ◎	25 ◎
Dispersibility in an oral cavity		4.3 ○	4.8 ◎	3.3 △	3.3 △	2.8 △